

13 cont  
desogestrel,  
3-ketodesogestrel, or  
dienogest,

or a mixture thereof.

### REMARKS

Applicants thank the Examiner for her careful attention to detail in pointing out allegedly unclear claim recitations, and have amended many of the claims as suggested.

? Claim 47 was an inadvertent duplicate of claim 31 and has thus been canceled.

✓ Typographical and/or clerical errors in claims 5, 10, 11, 24 and 25 have been corrected. The amendments do not change the scope of the claims and were not needed to establish patentability – only to expedite prosecution.

✓ Claims 12 and 26 have not been amended. One of skill in the art would recognize that the recitation “another gestagen” clearly means “a gestagen other than the four gestagens listed previously in the claim.” There is no need to amend the claims to the latter, somewhat awkward, recitation.

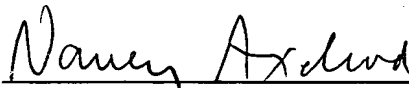
The allegation that DE 4344463A1 anticipates claims 1-12 and 15-26 is in error. This German patent is related to WO95/17193 (also in the German language) and to the U.S. national phase application of that PCT, Ser No: 08/666,592, now USP 6,225,297. For simplicity, the latter (English language) version will be referred to in the ensuing discussion. The ‘297 patent is drawn, e.g., to a product that contains in combination a progesterone antagonist and a gestagen “in which the amount of the competitive progesterone antagonist in each of its individual dosage units is non-ovulating inhibiting and non-abortion-inducing.” See, e.g., claim 1 of that patent. By contrast, instant claim 1 recites a combination in which the “competitive progesterone antagonist [is] in an amount effective to inhibit ovulation.”

As for the rejections over DE 4344405A1, which is related to WO 95/17895 (also in the German language, except for an English language abstract), applicants are currently seeking a translation of the relevant contents of the reference. However, an evaluation of the English language Abstract, alone, shows that the ‘895 PCT neither anticipates nor renders obvious the claimed invention. The Abstract discloses a packaging unit which comprises two hormone components, one of which “is essentially exclusively an estrogen preparation...” and

the other of which contains "an estrogen preparation plus a dose of a gestagen preparation." This combination in no way resembles the instantly claimed composition (*e.g.*, claims 29, 31, 32 and 39), which comprises two hormone components, one of which comprises a competitive progesterone antagonist and the other, a gestagen. To be anticipatory, a reference must disclose every material element of a claim (*In re Marshall*, 198 USPQ 344, (CCPA 1978), which this reference clearly does not. Nor does the reference render claims 30 and 38 obvious, at least because the Examiner has presented no reasons why the packaging unit (kit) of the reference suggests or discloses the kit of those claims. Even if the reference were to disclose "a slight structural change to claim 29" (which is not admitted), as the Examiner alleges, the reference fails to disclose the features of, *e.g.*, claim 29.

Therefore, the rejections should be withdrawn.

Respectfully submitted,



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Anthony J. Zelano (Reg. No. 27,969)  
Attorney for Applicant(s)

Nancy J. Axelrod (Reg. No. 44,014)  
Patent Agent

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.  
Arlington Courthouse Plaza I, Suite 1400  
2200 Clarendon Boulevard  
Arlington, Virginia 22201  
(703) 812-5304 [Direct Dial]  
(703) 243-6410 [Facsimile]  
Internet Address: axelrod@mwzb.com

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MARKED-UP VERSION

5. (Amended) A multi-phase combination preparation of claim 1, wherein the second phase comprises 7 to 14 daily dosage units.

10. (Amended) A multi-phase combination preparation of claim 1, wherein the competitive progesterone antagonist is ~~selected from~~:

17 $\alpha$ -ethinyl-17 $\beta$ -hydroxy-11 $\beta$ -(4-methoxyphenyl)estra-4,9-dien-3-one,  
11 $\beta$ -(4-acetylphenyl)-17 $\beta$ -hydroxy-17 $\alpha$ -(1-propenyl)estra-4,9-dien-3-one,  
(Z)-11 $\beta$ -(4-acetylphenyl)-17 $\beta$ -hydroxy-17 $\alpha$ -(3-hydroxy-1-propenyl)estra-4,9-dien-3-one,  
11 $\beta$ -(4-dimethylaminophenyl)-17 $\beta$ -hydroxy-17 $\alpha$ -(1-propinyl)estra-4,9-dien-3-one,  
(Z)-9,11 $\alpha$ -dihydro-17 $\beta$ -hydroxy-17 $\alpha$ -(3-hydroxy-1-propenyl)-6'-(3-pyridinyl)-4'*H*-naphth[3',2',1': 10,9,11]estra-4,9(11)-dien-3-one,  
(Z)-11 $\beta$ -[4-(dimethylamino)phenyl]-17 $\beta$ -hydroxy-17 $\alpha$ -(3-hydroxy-1-propenyl)-estr-4-en-3-one,  
4',5'-dihydro-11 $\beta$ -[4-(dimethylamino)phenyl]-6 $\beta$ -methylspiro[estra-4,9-dien-17 $\beta$ , 2'(3'*H*)-furan]-3-one,  
4',5'-dihydro-11 $\beta$ -[4-(dimethylamino)phenyl]-7 $\beta$ -methylspiro[estra-4,9-dien-17 $\beta$ , 2'(3'*H*)-furan]-3-one, or  
11 $\beta$ -(4-acetylphenyl)-19,24-dinor-17,23-epoxy-17 $\alpha$ -chola-4,9,20-trien-3-one,  
or a mixture thereof.

11. (Amended) A multi-phase combination preparation of claim 1, wherein the gestagen is ~~selected from~~:

gestodene,  
progesterone,  
levonorgestrel,  
cyproterone acetate,

chlormadinone acetate,  
drospirenone (dihydrospirorenone),  
norethisterone,  
norethisterone acetate,  
norgestimate,  
desogestrel,  
3-ketodesogestrel, or  
dienogest,

or a mixture thereof.

24. (Amended) A contraceptive kit of claim 15, wherein the competitive progesterone antagonist is ~~selected from~~:

17 $\alpha$ -ethinyl-17 $\beta$ -hydroxy-11 $\beta$ -(4-methoxyphenyl)estra-4,9-dien-3-one,  
11 $\beta$ -(4-acetylphenyl)-17 $\beta$ -hydroxy-17 $\alpha$ -(1-propenyl)estra-4,9-dien-3-one,  
(Z)-11 $\beta$ -(4-acetylphenyl)-17 $\beta$ -hydroxy-17 $\alpha$ -(3-hydroxy-1-propenyl)estra-4,9-dien-3-one,  
11 $\beta$ -(4-dimethylaminophenyl)-17 $\beta$ -hydroxy-17 $\alpha$ -(1-propinyl)estra-4,9-dien-3-one,  
(Z)-9,11 $\alpha$ -dihydro-17 $\beta$ -hydroxy-17 $\alpha$ -(3-hydroxy-1-propenyl)-6'-(3-pyridinyl)-4'*H*-naphth[3',2',1': 10,9,11]estra-4,9(11)-dien-3-one,  
(Z)-11 $\beta$ -[4-(dimethylamino)phenyl]-17 $\beta$ -hydroxy-17 $\alpha$ -(3-hydroxy-1-propenyl)-estr-4-en-3-one,  
4',5'-dihydro-11 $\beta$ -[4-(dimethylamino)phenyl]-6 $\beta$ -methylspiro[estra-4,9-dien-17 $\beta$ , 2'(3'*H*)-furan]-3-one,  
4',5'-dihydro-11 $\beta$ -[4-(dimethylamino)phenyl]-7 $\beta$ -methylspiro[estra-4,9-dien-17 $\beta$ , 2'(3'*H*)-furan]-3-one, or  
11 $\beta$ -(4-acetylphenyl)-19,24-dinor-17,23-epoxy-17 $\alpha$ -chola-4,9,20-trien-3-one,  
or a mixture thereof.

25. (Amended) A contraceptive kit of claim 15, in which the gestagen is ~~selected~~  
~~from~~:

gestodene,  
progesterone,  
levonorgestrel,  
cyproterone acetate,  
chlormadinone acetate,  
drospirenone (dihydrospirorenone),  
norethisterone,  
norethisterone acetate,  
norgestimate,  
desogestrel,  
3-ketodesogestrel, or  
dienogest,

or a mixture thereof.